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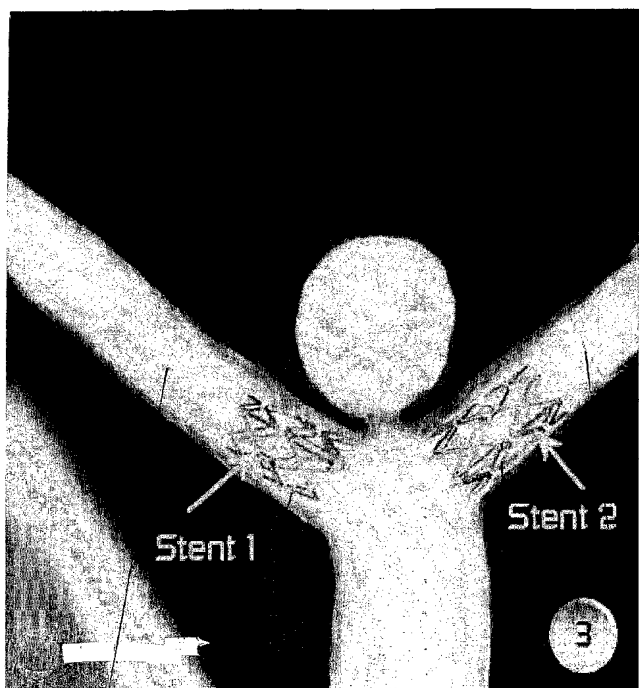
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(54) Title: A METHOD FOR TREATING ANEURYSMS



(57) Abstract: A Method For Treating Aneurysms A method for treating a bifurcation aneurysm, the aneurysm having an aneurysm neck, the method comprising positioning a first mechanically expandable device in a first bifurcation branch proximate to the aneurysm neck; positioning a second mechanically expandable device in a second bifurcation branch proximate to the aneurysm neck; and expanding the mechanically expandable devices to constrict the aneurysm neck such that blood circulation to the bifurcation aneurysm is reduced.

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**Title****A Method for Treating Aneurysms****Technical Field**

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The invention concerns a method for treating bifurcation or trifurcation aneurysms. In particular, the method is suitable for bifurcation or trifurcation aneurysms with wide aneurysm necks.

10 **Background of the Invention**

An aneurysm is a bulge or a weakening of a wall of an artery. An aneurysm usually occurs where one main blood vessel splits into two (bifurcation) or three smaller vessels (trifurcation). Bifurcation aneurysms account for approximately 35% of all cases of intracranial hemorrhagic disease.

Aneurysms may burst and cause bleeding into a covering around the brain called the subarachnoid space. This is referred to as a subarachnoid hemorrhage. Subarachnoid hemorrhage secondary to a ruptured aneurysm causes a severe headache.

Therefore, there is a desire for minimally invasive, less traumatic methods to treat bifurcation and trifurcation aneurysms.

25 **Summary of the Invention**

In a first preferred aspect, there is provided a method for treating a bifurcation aneurysm, the aneurysm having an aneurysm neck, the method comprising:

- positioning a first mechanically expandable device in a first bifurcation branch proximate to the aneurysm neck;
- positioning a second mechanically expandable device in a second bifurcation branch proximate to the aneurysm neck; and
- expanding the mechanically expandable devices to constrict the aneurysm neck such that blood circulation to the bifurcation aneurysm is reduced.

35

The aneurysm neck may be constricted such that blood circulation to the aneurysm is completely interrupted.

The mechanically expandable devices may be stents.

5 The stents may be mechanically expanded such that blood circulation to the bifurcation aneurysm via the aneurysm neck may be occluded.

10 The aneurysm may be reduced further in size by deploying gels or using coils. Where the aneurysm neck is wide, coils or securing glues may be deployed inside the aneurysm to reduce blood circulation inside the aneurysm. An aneurysm neck may be wide if the ratio of the diameter of the dome of the aneurysm to the width of the aneurysm neck is less than two.

The stents may be balloon expandable or self-expandable.

15 The stents may have markers to facilitate precise positioning in the branches. The markers may be placed at the distal and proximal ends of the stents. The markers may be radiopaque. The markers may be made from gold or platinum.

The stents may be positioned in the branches sequentially.

20 The stents may be expanded at the same time. Alternatively, the stents may be expanded sequentially.

The stent may be tapered towards the distal end of the stent. The stent may have a trapezoidal longitudinal cross-section. The stent may have proximal end struts that are elongated relative to the remaining struts.

25 The first stent may be positioned partially within the first bifurcation branch such that a portion of the proximal end of the first stent is not introduced within the first bifurcation branch.

30 The second stent may be positioned partially within the second bifurcation branch such that a portion of the proximal end of the second stent is not introduced within the second bifurcation branch.

35 A balloon of a balloon catheter may be used to expand the stent during deployment. The balloon may be tapered such that the proximal end of the stent is expanded first during deployment. Advantageously, this allows the aneurysm neck to be bridged with greater effectiveness.

The balloon may be made of soft durometer thin nylon or silicon.

The first stent may be expanded by a first balloon and the second stent may be expanded by a second balloon. The first and second balloons may be on a single shaft of a balloon catheter. The stents may be expanded at the same time during  
5 deployment.

Additional angioplasty balloon expansion may be used to secure the deployment of the stents.

The stents may be connected by a membrane for obstructing blood circulation to  
10 the bifurcation aneurysm. The membrane may comprise at least one layer of an elastomeric polymer. The membrane may comprise receptacles for carrying drugs or reagents for subsequent release after the stents are deployed. The drugs or reagents may include substances that reduce the thrombogenic, inflammatory or smooth muscle cell proliferative response of the vessel to the implantable medical  
15 devices. For example, cell inhibitors can be delivered in order to inhibit smooth muscle cells proliferation. In intracranial or some other applications fibrin sealants can be used and delivered to seal aneurysm neck and provide fibroblasts and endothelial cells growth. Specific examples of drugs or reagents may include heparin, phosphorylcholine, albumin, dexamethasone, paclitaxel and vascular  
20 endothelial growth factor (VEGF).

In a second aspect, there is provided a method for treating a trifurcation aneurysm, the aneurysm having an aneurysm neck, the method comprising:

- 25 positioning a first mechanically expandable device in a first trifurcation branch proximate to the aneurysm neck;
- positioning a second mechanically expandable device in a second trifurcation branch proximate to the aneurysm neck;
- positioning a third mechanically expandable device in a third trifurcation branch proximate to the aneurysm neck; and
- 30 expanding the mechanically expandable devices to constrict the aneurysm neck such that blood circulation to the trifurcation aneurysm is reduced.

The first mechanically expandable device may be positioned partially within the first trifurcation branch such that a portion of the proximal end of the first mechanically  
35 expandable device is not introduced within the first trifurcation branch.

The second mechanically expandable device may be positioned partially within the second trifurcation branch such that a portion of the proximal end of the second

mechanically expandable device is not introduced within the second trifurcation branch.

The third mechanically expandable device may be positioned partially within the third trifurcation branch such that a portion of the proximal end of the third  
5 mechanically expandable device is not introduced within the third trifurcation branch.

In a third aspect, there is provided a system for treating a bifurcation aneurysm, the aneurysm having an aneurysm neck, the system comprising:

10 a first mechanically expandable device positioned in a first bifurcation branch proximate to the aneurysm neck;

a second mechanically expandable device positioned in a second bifurcation branch proximate to the aneurysm neck; and

15 wherein the mechanically expandable devices are expanded to constrict the aneurysm neck such that blood circulation to the bifurcation aneurysm is reduced.

In a fourth aspect, there is provided a system for treating a trifurcation aneurysm, the aneurysm having an aneurysm neck, the system comprising:

20 a first mechanically expandable device positioned in a first trifurcation branch proximate to the aneurysm neck;

a second mechanically expandable device positioned in a second trifurcation branch proximate to the aneurysm neck;

25 a third mechanically expandable device positioned in a third trifurcation branch proximate to the aneurysm neck; and

wherein the mechanically expandable devices are expanded to constrict the aneurysm neck such that blood circulation to the trifurcation aneurysm is reduced.

30 In a fifth aspect, there is provided a mechanically expandable device for treating a bifurcation or trifurcation aneurysm, the aneurysm having an aneurysm neck, the device comprising:

a generally tubular structure having an exterior surface defined by a plurality of interconnected struts having interstitial spaces therebetween, said  
35 generally tubular structure expandable from a first position to a second position, and said tubular structure is expanded radially outwardly to the second position such that the exterior surface of said structure engages with the inner surface of a

bifurcation or trifurcation branch so as to maintain a fluid pathway through said branch and to constrict the aneurysm neck such that blood circulation to the aneurysm is reduced;

5 wherein a proximal portion of the struts are elongated relative to the remaining struts such that the device is tapered towards its distal end after deployment in the branch.

In a sixth aspect, there is provided a balloon for expanding a mechanically expandable device for treating a bifurcation or trifurcation aneurysm, the balloon  
10 being connected to a balloon catheter for inflation, and the device comprising a interconnected struts at its proximal end that are elongated relative to the remaining struts of the device such that the device is tapered towards its distal end after deployment in a bifurcation or trifurcation branch;

15 wherein the balloon is tapered towards its distal end after inflation, and the inflation of the balloon causes the elongated struts of the device to expand at a greater rate than the remaining struts for constricting the aneurysm neck such that blood circulation to the aneurysm is reduced.

20 The balloon may be a first balloon used in combination with a second balloon to expand a second mechanically expandable device in another bifurcation or trifurcation branch. The first balloon and second balloon may be inflated together via a single balloon catheter

#### **Brief Description of the Drawings**

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An example of the invention will now be described with reference to the accompanying drawings, in which:

Figure 1 is a pictorial representation of a bifurcation aneurysm;

Figure 2 is a pictorial representation of a stent deployed in a bifurcation branch;

30 Figure 3 is a pictorial representation of stents deployed in both bifurcation branches;

Figure 4 is a pictorial representation of a reduction of blood circulation to the bifurcation aneurysm when the stents are expanded;

35 Figure 5 is a pictorial representation of a tapered balloon to deploy the stent in a bifurcation branch;

Figure 6 is a pictorial representation of a tapered stent being deployed by a tapered balloon in a bifurcation branch;

Figure 7 is a pictorial representation of tapered stents deployed in both bifurcation branches;

Figure 8 is a pictorial representation of a tapered stent with elongated end struts when deployed;

5 Figure 9 is a pictorial representation of a tapered stent with elongated end struts before deployment;

Figure 10 is a pictorial representation of stents connected by a patch deployed in both bifurcation branches;

10 Figure 11 is a pictorial representation of stents with markers connected by a membrane deployed in both bifurcation branches;

Figure 12 is a pictorial representation of a tapered stent with elongated end struts and a marker before deployment;

Figure 13 is a pictorial representation of tapered stents with markers in both bifurcation branches being expanded by two connected tapered balloons;

15 Figure 14 is a pictorial representation of tapered stents with markers deployed in both bifurcation branches; and

Figure 15 is a pictorial representation of coils deployed in the aneurysm in addition to tapered stents with markers deployed in both bifurcation branches.

## 20 Detailed Description of the Drawings

Referring to Figures 1, a method for treating a bifurcation aneurysm 10 is shown. The aneurysm 10 has an aneurysm neck 11 where blood passes from a main artery 15 to the aneurysm 10. The aneurysm 10 is located at the end of the main artery 15 where it diverges into two bifurcation branches 12, 13. A first stent 20 is positioned in a first bifurcation branch 12 proximate to the aneurysm neck 11 as shown in Figure 2. Next, a second stent 21 is positioned in a second bifurcation branch 13 proximate to the aneurysm neck 11 as shown in Figure 3. The stents 12, 13 are expanded to constrict the aneurysm neck 11 such that blood circulation to the aneurysm 10 is reduced. In a bifurcation branch 12, 13, the side of the branch wall 12, 13 opposing the aneurysm neck 11 is more rigid relative to the branch wall 12, 13 adjacent to the aneurysm neck 11. Thus, when the stent 20, 30 is expanded, the majority of the expansion force is directed towards the branch wall 12, 13 adjacent to the aneurysm neck 11 which begins to constrict the aneurysm neck 11. Even if the aneurysm neck 11 is partially constricted, blood circulation to the aneurysm 10 is reduced. This eventually leads to the aneurysm 10 drying out from a reduction in blood circulation as shown in Figure 4.

Intracranial stents 20, 30 are designed to be very flexible, and have a low profile (0.033" to 0.034" or even less as crimped onto delivery catheter) and thin wall (0.0027" to 0.0028"). The intracranial stents 20, 30 feature low deployment  
5 pressure (3 to 4 atmospheres) and do not necessarily have the highest possible radial strength because there is no need for high strength in intracranial applications. In one example, the stents 20, 30 are made from platinum/iridium/tungsten alloys.

10 Stents 20, 30 are a generally tubular structure having an exterior surface defined by a plurality of interconnected struts 32 having interstitial spaces there between. The generally tubular structure is expandable from a first position, wherein the stent 20, 30 is sized for intravascular insertion, to a second position, wherein at least a portion of the exterior surface of the stent contacts the vessel wall 12, 13.  
15 The expansion of the stent 20, 30 is accommodated by flexing and bending of the interconnected struts 32 throughout the generally tubular structure. It is contemplated that many different stent designs can be produced. A myriad of strut patterns are known for achieving various design goals such as enhancing strength, maximizing the expansion ratio or coverage area, enhancing longitudinal flexibility  
20 or longitudinal stability upon expansion. One pattern may be selected over another in an effort to optimize those parameters that are of particular importance for a particular application.

In one example, the stent 20, 30 comprises stent struts 32 of a ring, ring  
25 connectors, and end markers 34. The stents 100 are made of multiple circumstantial rings, where the ring connectors connect two or three adjacent rings to hold the rings in place. In another example, a self-expanding stent 20, 30 is made of wires/ribbons. While a self-expanding stent may have many designs, one specific stent 20, 30 has a typical braided pattern with welded ends. The stent 20,  
30 30 is designed such that it is relatively flexible along its longitudinal axis to facilitate delivery through tortuous body lumens, but is sufficiently stiff and stable radially in an expanded condition to maintain the patency of a body lumen, such as an artery or bifurcation/trifurcation branch 12, 13 when implanted therein. When a tubular stent 20, 30 is fully expanded to its deployed diameter, the latticework of struts 32  
35 takes on a shape in which adjacent crests undergo wide separation, and portions of the struts 32 take on a transverse, almost fully lateral orientation relative to the longitudinal axis of the stent 20, 30. Such lateral orientation of a plurality of the

struts 32 enables each fully opened cell to contribute to the firm mechanical support offered by the stent 20, 30 in its fully deployed position, to assure a rigid structure which is highly resistant to recoil of the vessel wall 12, 13 following stent deployment. It bears emphasis, however, that the configuration of this stent structure, while highly desirable, is illustrative only.

Referring to Figures 5 to 9, tapered stents 30, 31 are used to further enhance constriction of the aneurysm neck 11. For the delivery system, a tapered balloon 35 of a balloon catheter 36 expands the tapered stents 30, 31 by inflation, after the stents 30, 31 are placed into position in a respective bifurcation branch 12, 13. At the proximal end of the tapered stents 30, 31 there are elongated struts 33 to provide the tapering effect. The elongated struts 33 expand at a greater rate relative to the non-elongated struts 32. Also, tapered stents 30, 31 after deployment have a profile which conforms to the opening of the bifurcation branch 12, 13 from the main artery 15. Figure 8 depicts a tapered stent 30 in an expanded state, typically when the stent 30 is deployed. Figure 9 depicts the tapered stent 30 in a compressed state, typically during delivery via the balloon catheter 36.

The delivery system includes a guide wire lumen, a balloon inflating lumen, a connector, a balloon catheter shaft, and platinum marker bands on the catheter shaft (not shown). The guide wire lumen is used for introducing a guide wire in a balloon catheter 36, and the balloon inflating lumen is used for inflating the balloon 35 after the stent 20, 30 to be placed reaches its targeted location. The connector is used for separating the guide wire lumen and the balloon inflating lumen. The balloon catheter shaft carries the guide wire lumen and the balloon inflating lumen separately, with a typical length ranging 135 to 170 cm. The ring markers on the catheter shaft are used for showing the start of balloon tapers 35 and the edges of the stent 20, 30.

The balloon 35 is formed of suitable materials such as irradiated polyethylene, polyethylene terephthalate, polyvinylchloride, nylon, and copolymer nylons such as Pebax™. Other polymers may also be used. In order for the stent 20, 30 to remain in place on the balloon 35 during delivery to the desired site within a branch 12, 13, the stent 20, 30 is crimped onto the balloon 35.

In a preferred embodiment, the delivery of the stent 20, 30 is accomplished in the following manner. The stent 20, 30 is first mounted onto the inflatable balloon 35

- on the distal extremity of the delivery catheter 36. The stent 20, 30 is mechanically crimped onto the exterior of the folded balloon 35. The catheter/stent assembly is introduced within vasculature through a guiding catheter. A guide wire is disposed across the diseased arterial section and then the catheter/stent assembly is
- 5 advanced over a guide wire within the branch 12, 13 until the stent 20, 30 reaches the desired position. The balloon 35 of the catheter 36 is expanded, expanding the stent 20, 30 against the branch wall 12, 13. The expanded stent serves to hold open the artery after the catheter is withdrawn. Due to the formation of the stent 20, 30 from an elongated tube, the undulating component of the cylindrical
- 10 elements of the stent 20, 30 is relatively flat in transverse cross-section, so that when the stent 20, 30 is expanded, the cylindrical elements are pressed against the wall of the branch 12, 13 and as a result do not interfere with the blood flow through the branch 12, 13. The cylindrical elements of the stent 20, 30 which are pressed into the wall of the branch 12, 13 is eventually covered with an endothelial
- 15 cell layer which further minimizes blood flow interference. Furthermore, the closely spaced cylindrical elements at regular intervals provide uniform support for the wall of the branch 12, 13, and consequently are well adopted to take up and hold in place small flaps or dissections in the wall of the branch 12, 13.
- 20 As described earlier, a stent 20, 30 may be deployed by radial expansion under outwardly directed radial pressure exerted. For example by active inflation of a balloon 35 of a balloon catheter 36 on which the stent 20, 30 is mounted. Another deployment method may rely on the stent 20, 30 being self-expandable. In some instances, passive spring characteristics of a preformed elastic (that is, self-
- 25 opening) stent 20, 30 serve the purpose. The stent 20, 30 is then expanded to engage the inner lining or inwardly facing surface of the vessel wall 12, 13 with sufficient resilience to allow some contraction but also with sufficient stiffness to largely resist the natural recoil of the vessel wall 12, 13.
- 30 For resilient or self-expanding stents 20, 30, they are deployed without dilation balloons 35. Self-expanding stents 20, 30 are pre-selected according to the diameter of the blood vessel, bifurcation/trifurcation branch 12, 13 or other intended fixation site. While stent deployment requires skill in stent positioning, such deployment does not require the additional skill of carefully dilating a balloon
- 35 35 to plastically expand the prosthesis to the appropriate diameter. Further, the self-expanding stent 20, 30 remains at least slightly elastically compressed after fixation, and has a restoring force which facilitates acute fixation. By contrast, a

plastically expanded stent 20, 30 must rely on the restoring force of deformed tissue, or on hooks, barbs, or other independent fixation elements.

5 Referring to Figure 15, in a further example, the aneurysm 10 is reduced further in size by deploying gels or using coils 50. If the aneurysm neck 11 is wide, coils 50 or securing glues (not shown) are deployed inside the aneurysm 10 to reduce blood circulation inside the aneurysm 10. An aneurysm neck 11 can be considered wide if the ratio of the diameter of the dome of the aneurysm 10 to the width of the aneurysm neck 11 is less than two.

10

Referring to Figure 10, a pair of stents 20, 21 are joined together by a membrane 25. The membrane 25 obstructs blood circulation to the aneurysm 10. The stents 20, 21 are an open cell design and have a variable profile. Thus in addition to constriction of the aneurysm neck 11 by the stents 20, 21, the presence of the  
15 membrane 25 also obstructs blood circulation through the aneurysm neck 11 and may hasten the drying out of the aneurysm 10.

In one example, the membrane 25 may comprise one or more layers of an elastomeric polymer. The membrane 25 may comprise a first layer and a second  
20 layer. Many polymeric materials are suitable for making the layers of the membrane 25. One such material may be elastomeric polyurethane. Typically, one first layer is disposed onto the outer surface of a stent 20, 30.

In certain embodiments, the first layer is an independent membrane to  
25 mechanically cover and seal the aneurysm 10. In certain embodiments, the first and/or second layers may be made from biodegradable material as a drug or reagent carrier for sustained release.

The intermediate layer may be formed of a material which fuses to the first and  
30 second layers or attached to the first layer in a different manner. In certain embodiments, the intermediate layer may be merged with the first layer to form a single layer with recessions within the outer surface of the merged layer.

In one embodiment, the second and intermediate layers are made of  
35 biodegradable material that contains drugs or reagents for immediate or sustained controlled release. After biodegradable material has degraded over time, the

membrane 25 is still in tact to provide vessel support. The second layer may be made from a polymeric material.

- 5 The polymeric layers of the membrane 25 may also be made from a material selected from the group consisting of fluoropolymers, polyimides, silicones, polyurethanes, polyurethanes ethers, polyurethane esters, polyurethaneureas and mixtures and copolymers thereof. Biodegradable polymeric materials can also be used.
- 10 Adhering, laminating, suturing or otherwise bonding fusible polymeric layers may be conducted. The fusion of the polymeric layers may be achieved by various techniques such as heat-sealing, solvent bonding, adhesive bonding or use of coatings.
- 15 The membrane 25 may further comprise pockets (not shown) serving as receptacles for drugs or reagents so that the drugs or reagents may be delivered into vascular systems. The membrane 25 may cover a part of a stent 20, 30, where the size of the membrane 25 may be varied in accordance with any specific application. In one extreme, the membrane 25 may cover the whole outer surface of a stent 20, 30. Thus, the membrane 25 may be in any shape or size. A drug or reagent can be injected in the form of a gel, liquid or powder into receptacles of the pockets. Alternatively the drug or reagent can be supplied in a powder which has been formed into a solid tablet positioned in the receptacles. Such tablets would gradually dissolve after implantation. The drugs or reagents include substances
- 20 that reduce the thrombogenic, inflammatory or smooth muscle cell proliferative response of the vessel to the implantable medical devices. For example, cell inhibitors can be delivered in order to inhibit smooth muscle cells proliferation. In intracranial or some other applications fibrin sealants can be used and delivered to seal aneurysm neck and provide fibroblasts and endothelial cells growth. Specific examples of drugs or reagents may include heparin, phosporylcholine, albumin, dexamethasone, paclitaxel and vascular endothelial growth factor (VEGF).
- 25
- 30

- Figures 11 and 12 show stents 20, 21, 30, 31 with markers 34. The markers 34 improve visibility as they are radiopaque and may be made from gold or platinum.
- 35 The markers 34 facilitate precise positioning and orientation of the stents 20, 30 during deployment in the branches 12, 13. The markers 34 may be end markers and are usually placed at the distal and proximal ends of the stents 20, 30. The

drawings show a disc shaped marker. However, the shape is not critical so long as the marker 34 can be used to improve visibility of the stent 20, 30. The markers may be center markers that are special type platinum star-shaped markers to assist in precise indication and alignment of the stents 20, 30 in relation to the aneurysm neck 11 and allow further operations with the aneurysm 10. Then, the markers located around the middle of the stent 20, 30. The center markers assist in locating an aneurysm opening during an implantation operation. The center markers can be made of the same material and have the same shape as the end markers.

10

Figure 13 shows tapered stents 30, 31 with markers 34 during deployment. The tapered stents 30, 31 are expanded by two balloons 35 via a single balloon catheter 36. After the tapered stents 30, 31 have been expanded the balloons 35 are deflated and the catheter 36 is retracted as shown in Figure 14.

15

Although a bifurcation aneurysm 10 has been described, it is envisaged that the present invention may be used for trifurcation aneurysms and the like.

20

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the scope or spirit of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects illustrative and not restrictive.

**WE CLAIM:**

1. A method for treating a bifurcation aneurysm, the aneurysm having an aneurysm neck, the method comprising:  
5       positioning a first mechanically expandable device in a first bifurcation branch proximate to the aneurysm neck;  
          positioning a second mechanically expandable device in a second bifurcation branch proximate to the aneurysm neck; and  
          expanding the mechanically expandable devices to constrict the aneurysm  
10   neck such that blood circulation to the bifurcation aneurysm is reduced.
2. The method according to claim 1, wherein the aneurysm neck is constricted such that blood circulation to the aneurysm is completely interrupted.
- 15   3. The method according to claim 1, wherein the mechanically expandable devices are stents.
4. The method according to claim 3, wherein the stents are mechanically expanded such that blood circulation to the bifurcation aneurysm via the aneurysm  
20   neck may be occluded.
5. The method according to claim 1, wherein the aneurysm is reduced further in size by deploying gels or using coils.
- 25   6. The method according to claim 1, wherein if the aneurysm neck is wide, coils or securing glues are deployed inside the aneurysm to reduce blood circulation inside the aneurysm.
7. The method according to claim 6, wherein an aneurysm neck is wide if the  
30   ratio of the diameter of the aneurysm dome to the width of the aneurysm neck is less than two.
8. The method according to claim 3, wherein the stents are balloon expandable or self-expandable.
- 35   9. The method according to claim 3, wherein the stents have markers to facilitate precise positioning in the branches.

10. The method according to claim 9, wherein the markers are placed at the distal and proximal ends of the stents.
- 5 11. The method according to claim 9, wherein the markers are radiopaque.
12. The method according to claim 9, wherein the markers are made from gold or platinum.
- 10 13. The method according to claim 3, wherein the stents are positioned in the branches sequentially.
14. The method according to claim 3, wherein the stents are expanded at the same time.
- 15 15. The method according to claim 3, wherein the stents are expanded sequentially.
16. The method according to claim 3, wherein the stent is tapered towards the distal end of the stent.
- 20 17. The method according to claim 3, wherein the stent has a trapezoidal longitudinal cross-section.
- 25 18. The method according to claim 16 or 17, wherein the stent has proximal end struts that are elongated relative to the remaining struts.
19. The method according to claim 3, wherein the first stent is positioned partially within the first bifurcation branch such that a portion of the proximal end of the first stent is not introduced within the first bifurcation branch.
- 30 20. The method according to claim 3, wherein the second stent is positioned partially within the second bifurcation branch such that a portion of the proximal end of the second stent is not introduced within the second bifurcation branch.
- 35 21. The method according to claim 3, wherein a balloon of a balloon catheter expands the stent during deployment.

22. The method according to claim 21, wherein the balloon is tapered such that the proximal end of the stent is expanded first during deployment.
- 5 23. The method according to claim 21, wherein the balloon is made of soft durometer thin nylon or silicon.
24. The method according to claim 3, wherein the first stent is expanded by a first balloon and the second stent is expanded by a second balloon.
- 10 25. The method according to claim 24, wherein the first and second balloons are on a single shaft of a balloon catheter.
26. The method according to claim 24, wherein the stents are expanded at the same time during deployment.
- 15 27. The method according to claim 24, wherein additional angioplasty balloon expansion is used to secure the deployment of the stents.
- 20 28. The method according to claim 3, wherein the stents are connected by a membrane for obstructing blood circulation to the bifurcation aneurysm.
29. The method according to claim 28, wherein the membrane comprises at least one layer of an elastomeric polymer.
- 25 30. The method according to claim 29, wherein the membrane comprises receptacles for carrying drugs or reagents for subsequent release after the stents are deployed.
- 30 31. The method according to claim 30, wherein the drugs or reagents include substances that reduce the thrombogenic, inflammatory or smooth muscle cell proliferative response of the vessel to the implantable medical devices.
- 35 32. The method according to claim 31, wherein the substances include cell inhibitors to inhibit smooth muscle cells proliferation.

33. The method according to claim 31, wherein the substances include fibrin sealants to seal aneurysm neck and provide fibroblasts and endothelial cells growth.
- 5 34. The method according to claim 30, wherein the drugs or reagents include heparin, phosphorylcholine, albumin, dexamethasone, paclitaxel and vascular endothelial growth factor (VEGF).
- 10 35. A method for treating a trifurcation aneurysm, the aneurysm having an aneurysm neck, the method comprising:  
positioning a first mechanically expandable device in a first trifurcation branch proximate to the aneurysm neck;  
positioning a second mechanically expandable device in a second trifurcation branch proximate to the aneurysm neck;  
15 positioning a third mechanically expandable device in a third trifurcation branch proximate to the aneurysm neck; and  
expanding the mechanically expandable devices to constrict the aneurysm neck such that blood circulation to the trifurcation aneurysm is reduced.
- 20 36. The method according to claim 35, wherein the first mechanically expandable device is positioned partially within the first trifurcation branch such that a portion of the proximal end of the first mechanically expandable device is not introduced within the first trifurcation branch.
- 25 37. The method according to claim 35, wherein the second mechanically expandable device is positioned partially within the second trifurcation branch such that a portion of the proximal end of the second mechanically expandable device is not introduced within the second trifurcation branch.
- 30 38. The method according to claim 35, wherein the third mechanically expandable device is positioned partially within the third trifurcation branch such that a portion of the proximal end of the third mechanically expandable device is not introduced within the third trifurcation branch.
- 35 39. A system for treating a bifurcation aneurysm, the aneurysm having an aneurysm neck, the system comprising:

a first mechanically expandable device positioned in a first bifurcation branch proximate to the aneurysm neck;

a second mechanically expandable device positioned in a second bifurcation branch proximate to the aneurysm neck; and

5        wherein the mechanically expandable devices are expanded to constrict the aneurysm neck such that blood circulation to the bifurcation aneurysm is reduced.

40.     A system for treating a trifurcation aneurysm, the aneurysm having an aneurysm neck, the system comprising:

10        a first mechanically expandable device positioned in a first trifurcation branch proximate to the aneurysm neck;

      a second mechanically expandable device positioned in a second trifurcation branch proximate to the aneurysm neck;

15        a third mechanically expandable device positioned in a third trifurcation branch proximate to the aneurysm neck; and

      wherein the mechanically expandable devices are expanded to constrict the aneurysm neck such that blood circulation to the trifurcation aneurysm is reduced.

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41.     A mechanically expandable device for treating a bifurcation or trifurcation aneurysm, the aneurysm having an aneurysm neck, the device comprising:

      a generally tubular structure having an exterior surface defined by a plurality of interconnected struts having interstitial spaces therebetween, said  
25        generally tubular structure expandable from a first position to a second position, and said tubular structure is expanded radially outwardly to the second position such that the exterior surface of said structure engages with the inner surface of a bifurcation or trifurcation branch so as to maintain a fluid pathway through said branch and to constrict the aneurysm neck such that blood circulation to the  
30        aneurysm is reduced;

      wherein a proximal portion of the struts are elongated relative to the remaining struts such that the device is tapered towards its distal end after deployment in the branch.

35     42.     A balloon for expanding a mechanically expandable device for treating a bifurcation or trifurcation aneurysm, the balloon being connected to a balloon catheter for inflation, and the device comprising a interconnected struts at its

proximal end that are elongated relative to the remaining struts of the device such that the device is tapered towards its distal end after deployment in a bifurcation or trifurcation branch;

5        wherein the balloon is tapered towards its distal end after inflation, and the inflation of the balloon causes the elongated struts of the device to expand at a greater rate than the remaining struts for constricting the aneurysm neck such that blood circulation to the aneurysm is reduced.

43.        The balloon according to claim 42, wherein the balloon is a first balloon  
10        used in combination with a second balloon to expand a second mechanically expandable device in another bifurcation or trifurcation branch.

44.        The balloon according to claim 43, wherein the first balloon and second balloon are inflated together via a single balloon catheter.

Figure 1

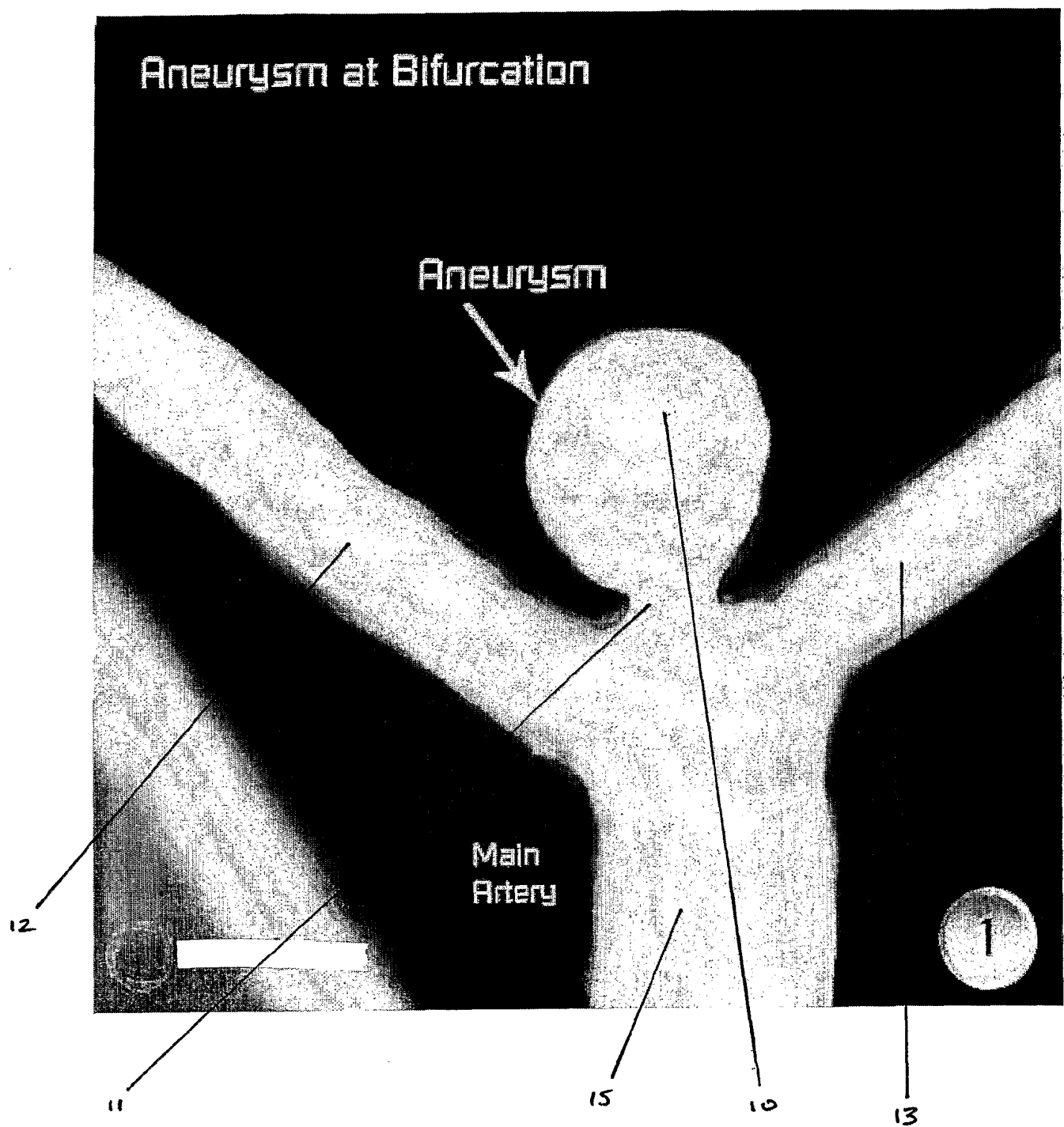


Figure 2

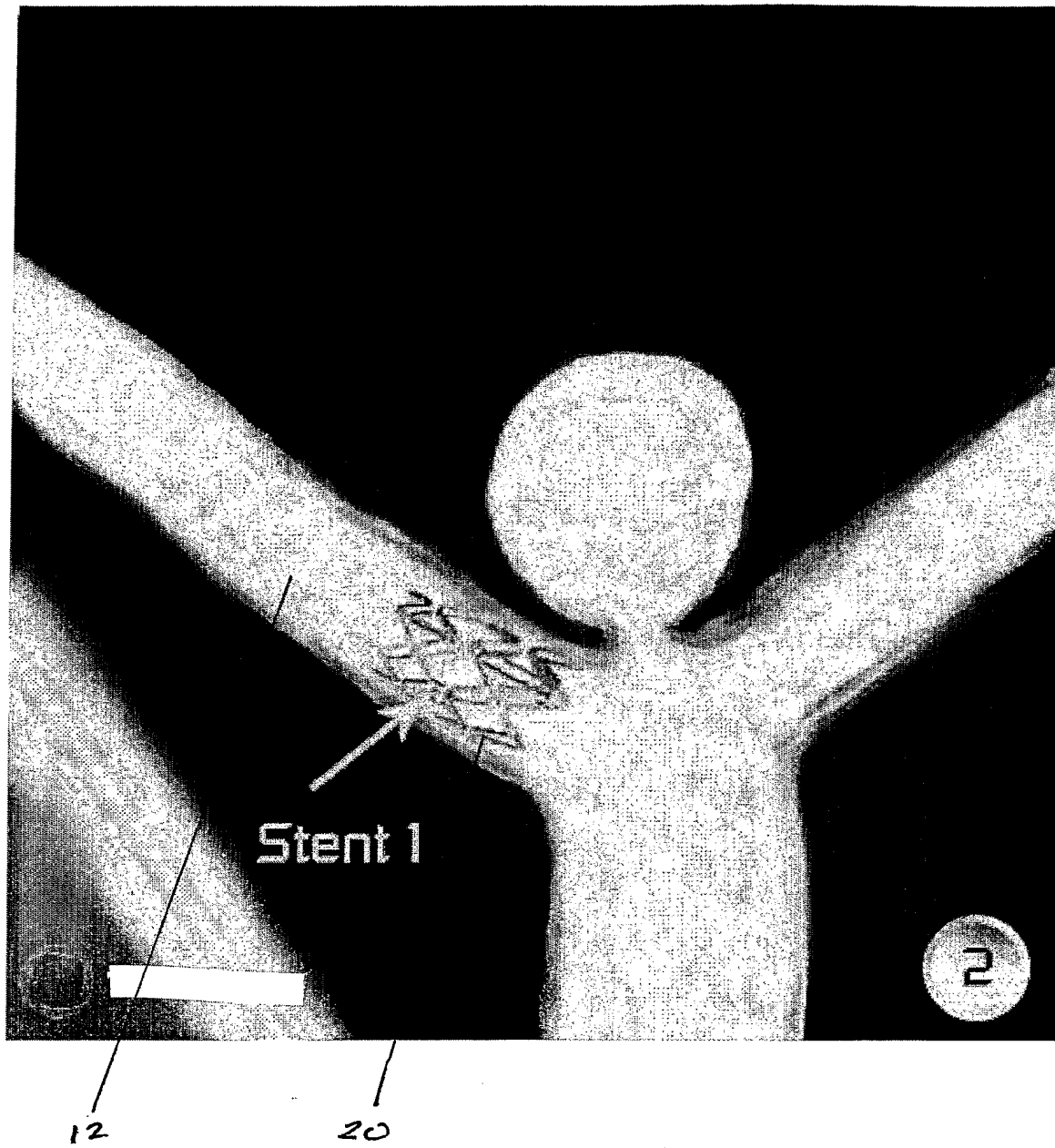


Figure 3

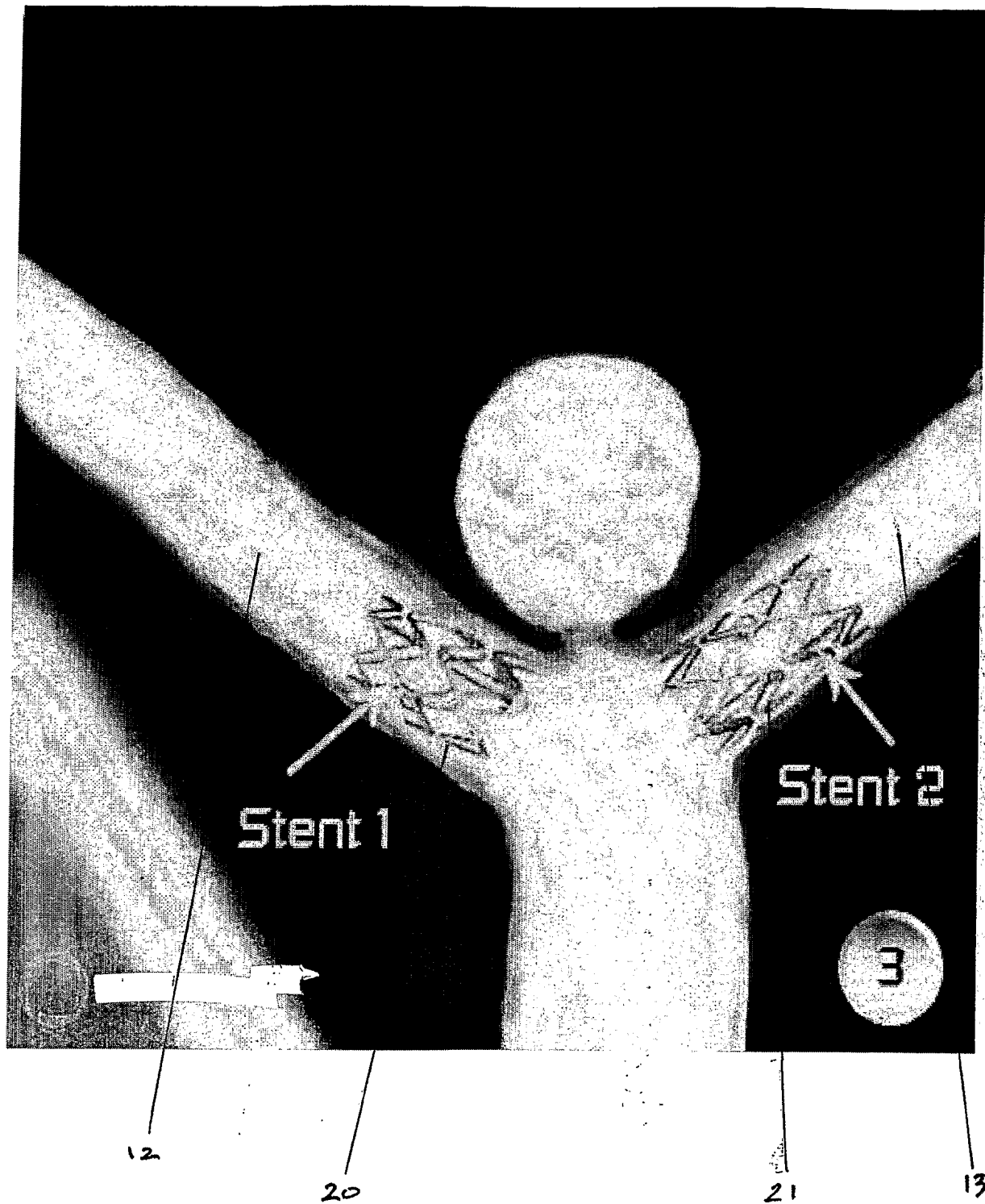
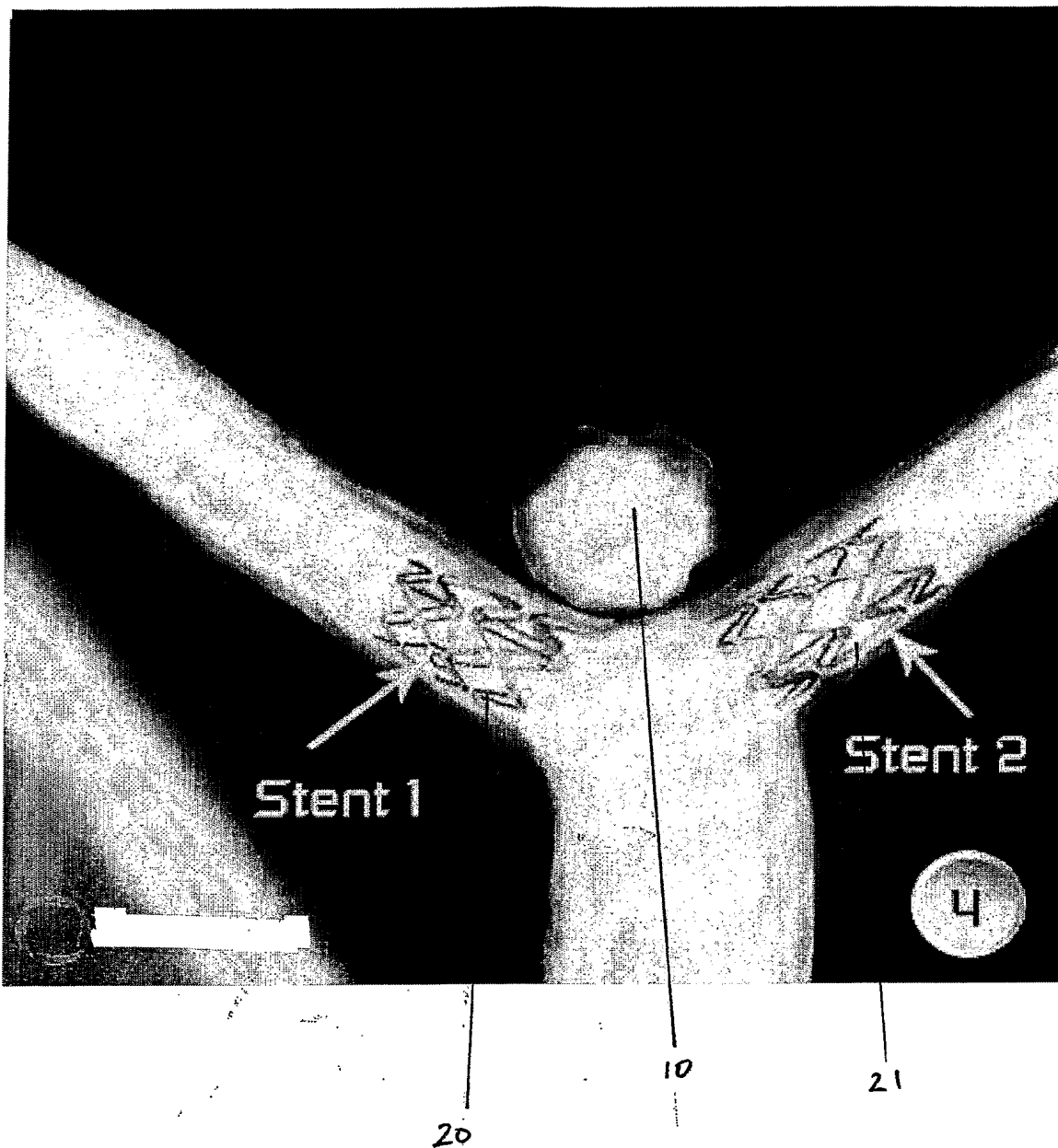
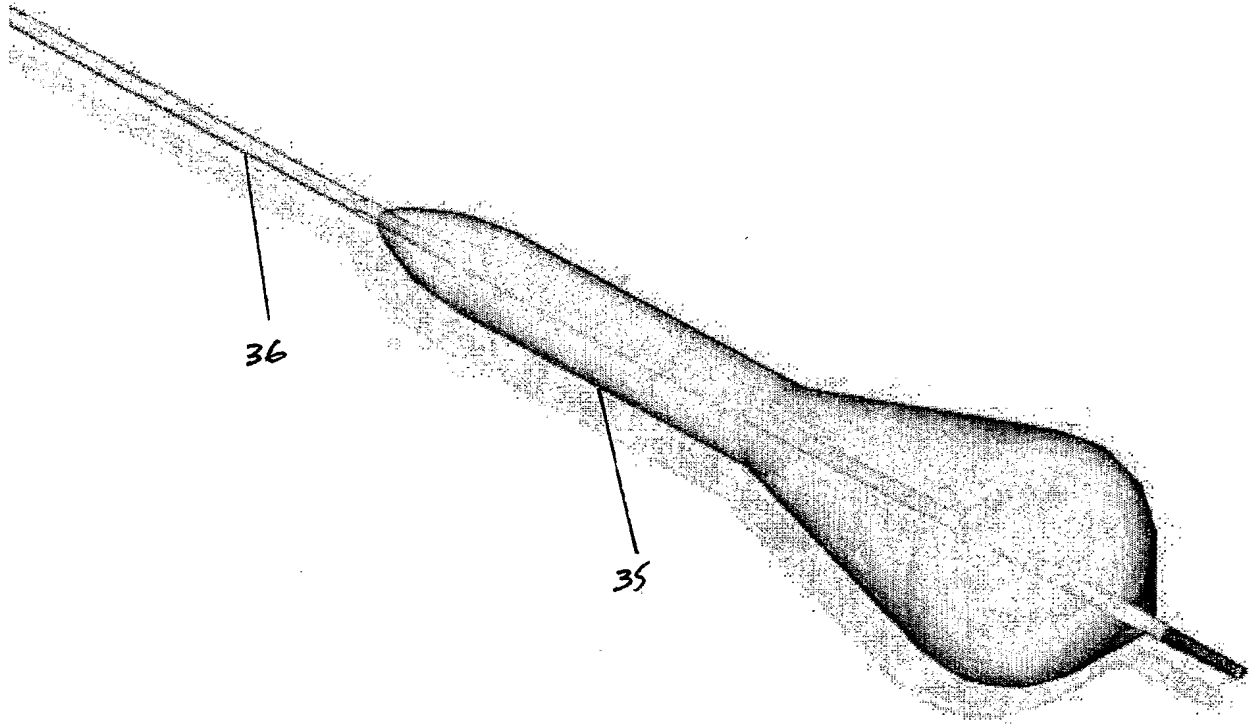


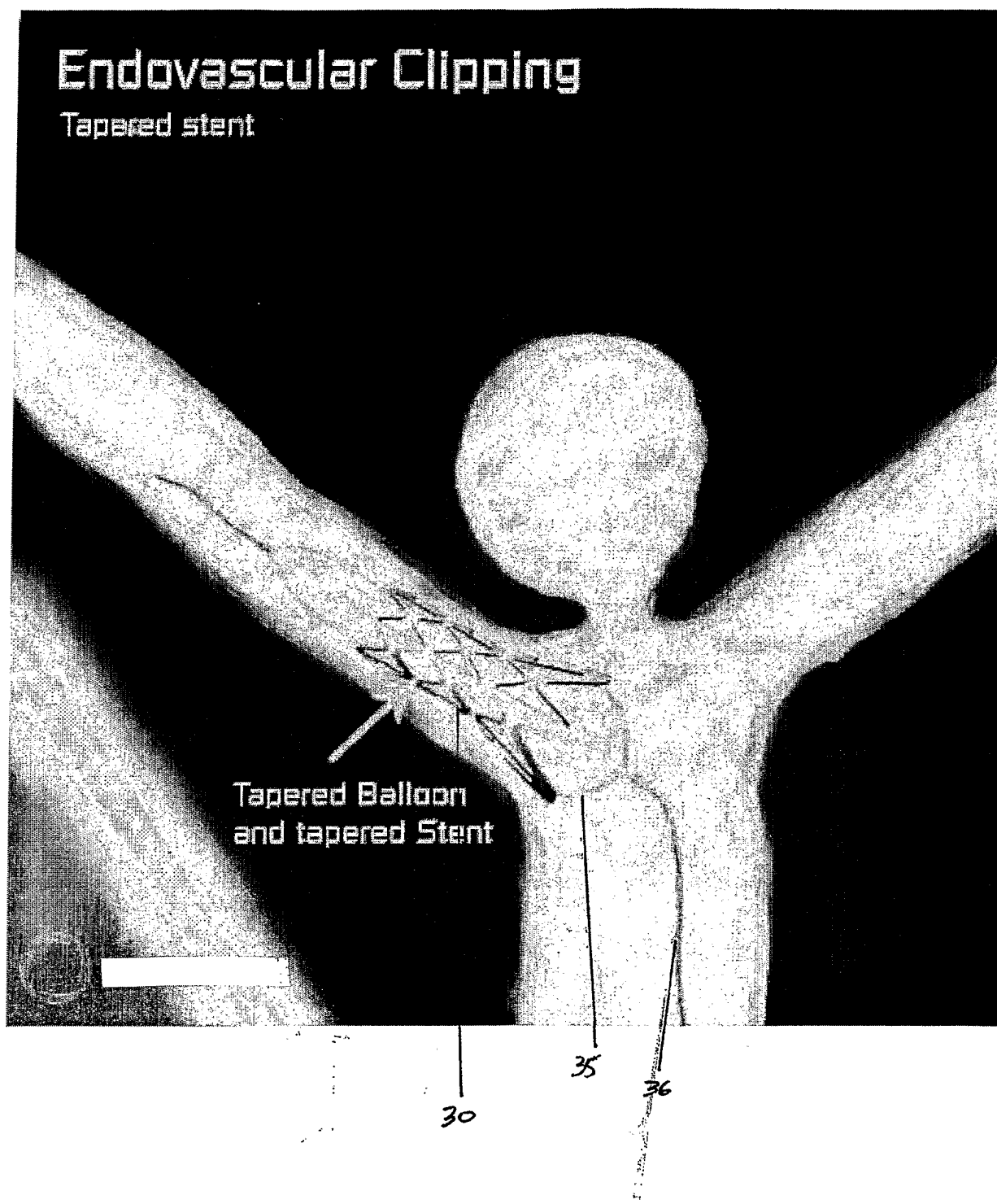
Figure 4



**Figure 5**



### Figure 6



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Figure 7

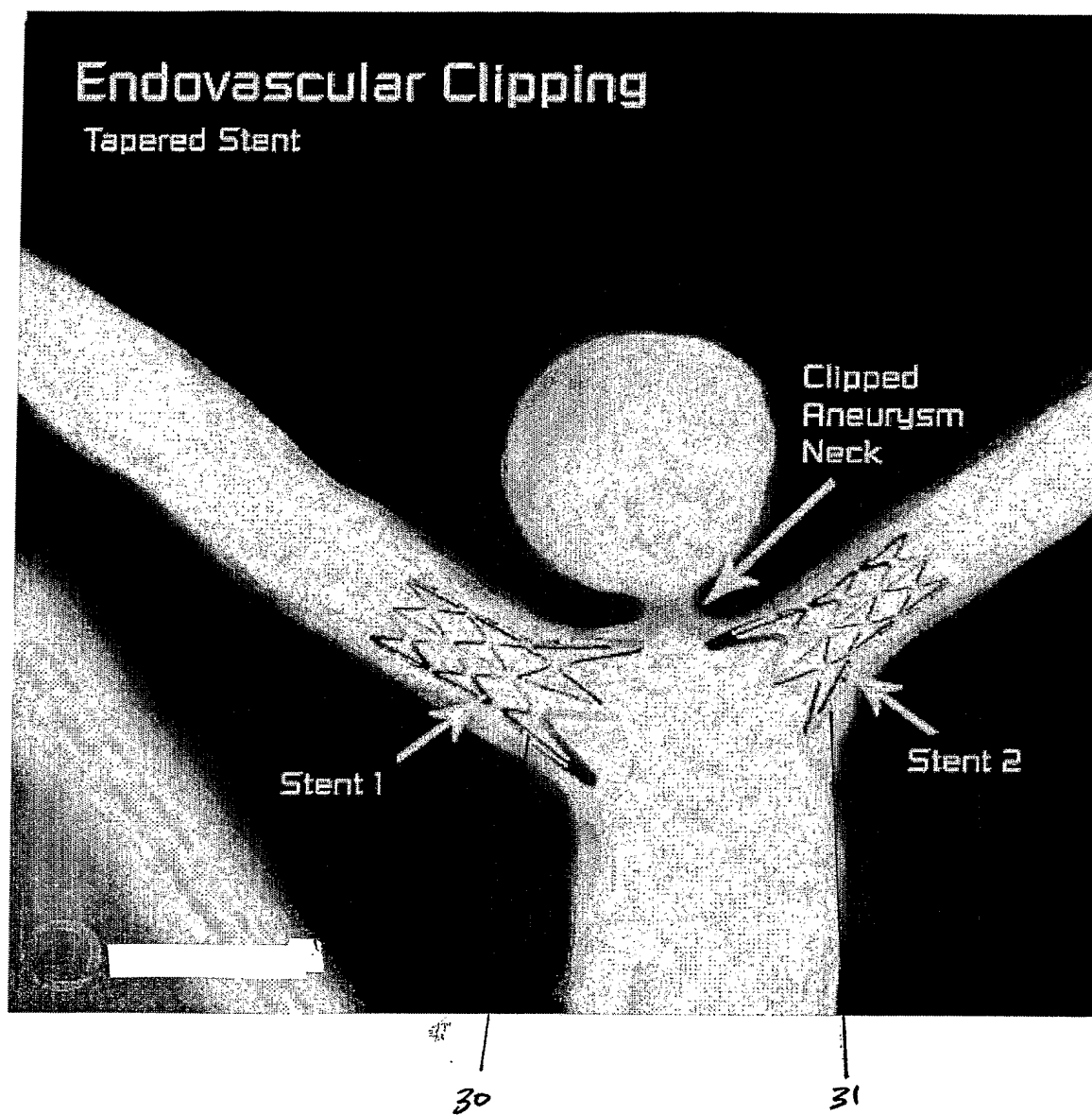


Figure 8

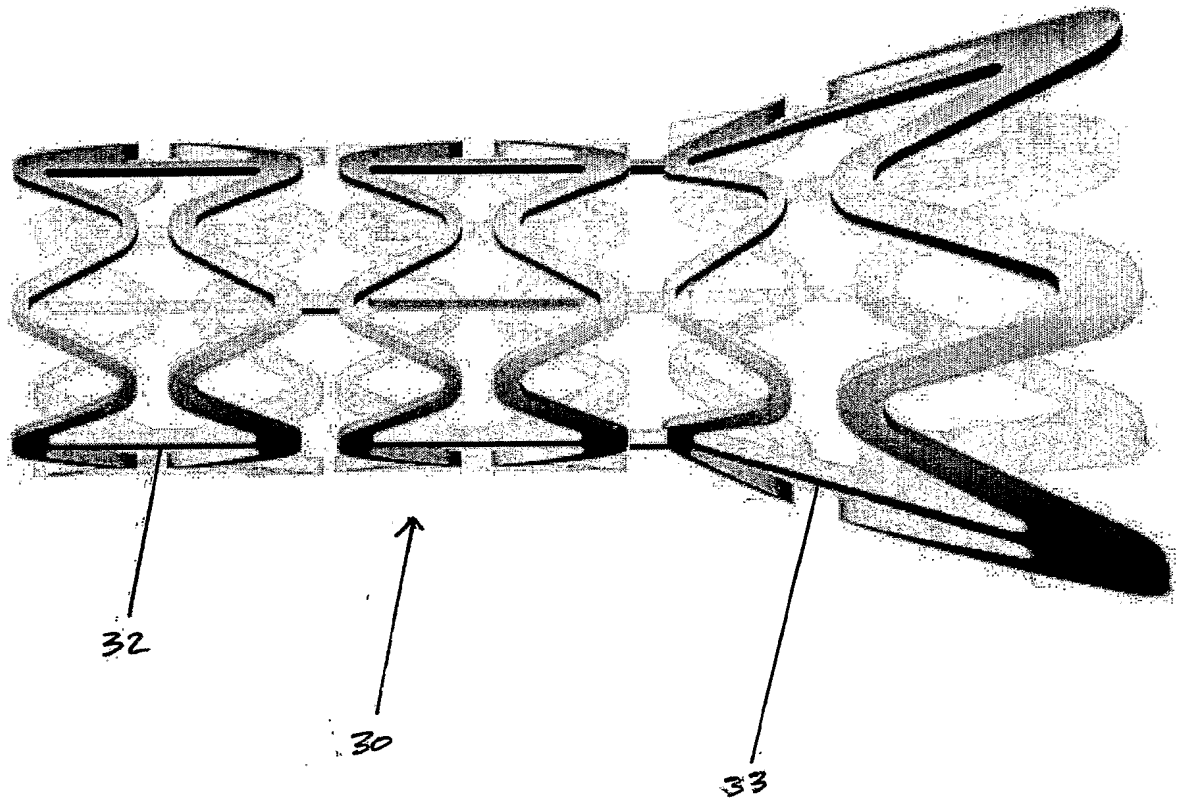
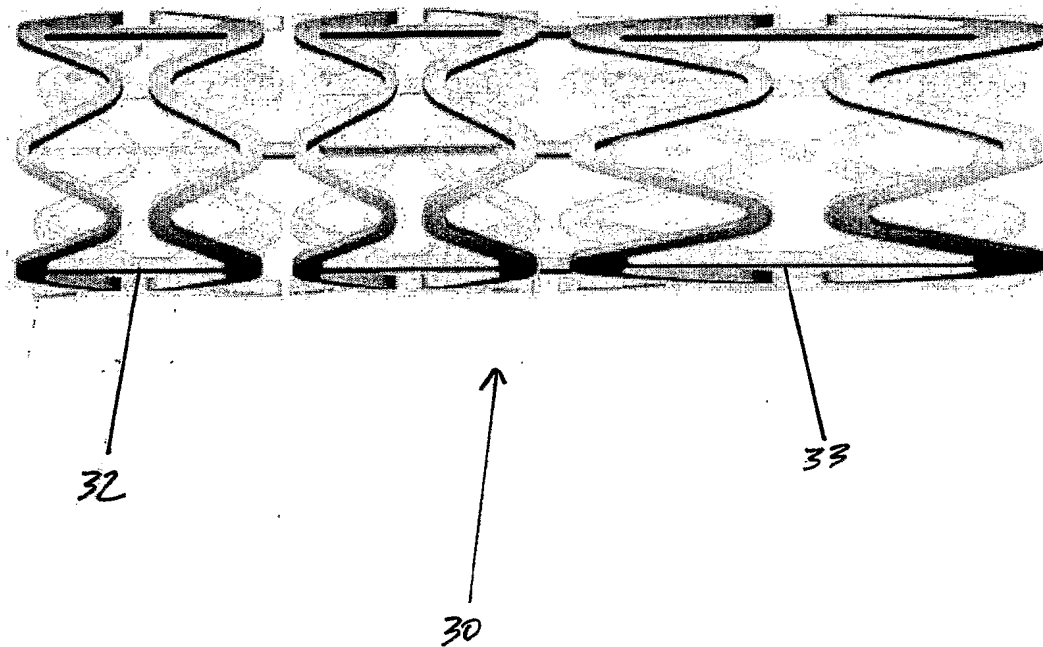


Figure 9



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Figure 10

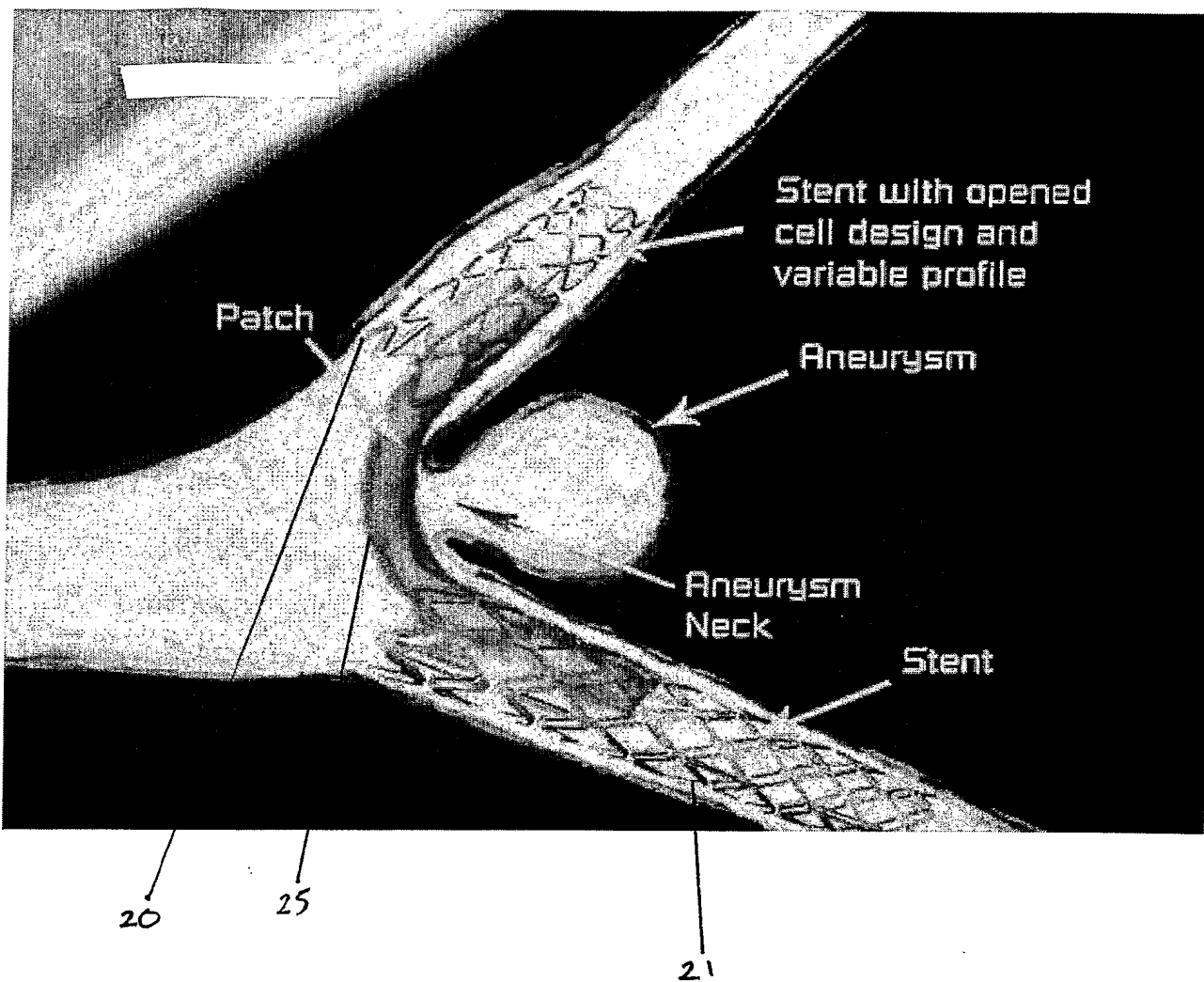
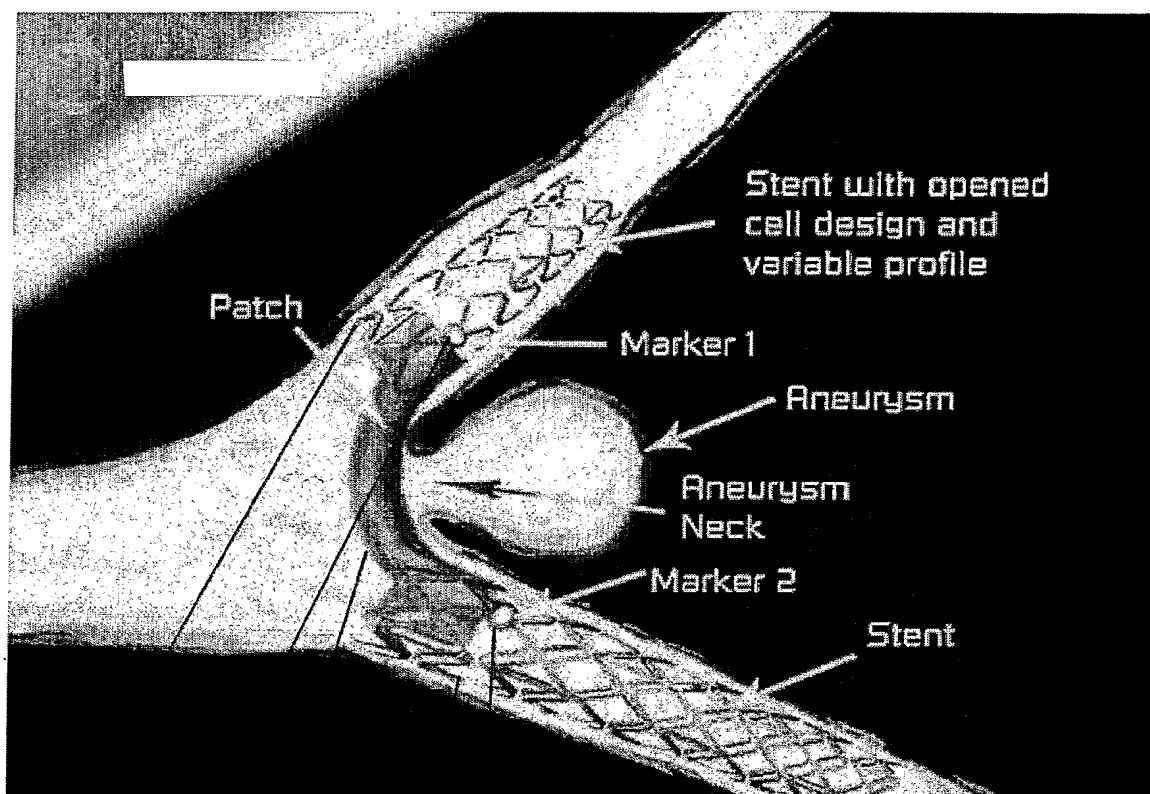


Figure 11



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Figure 12

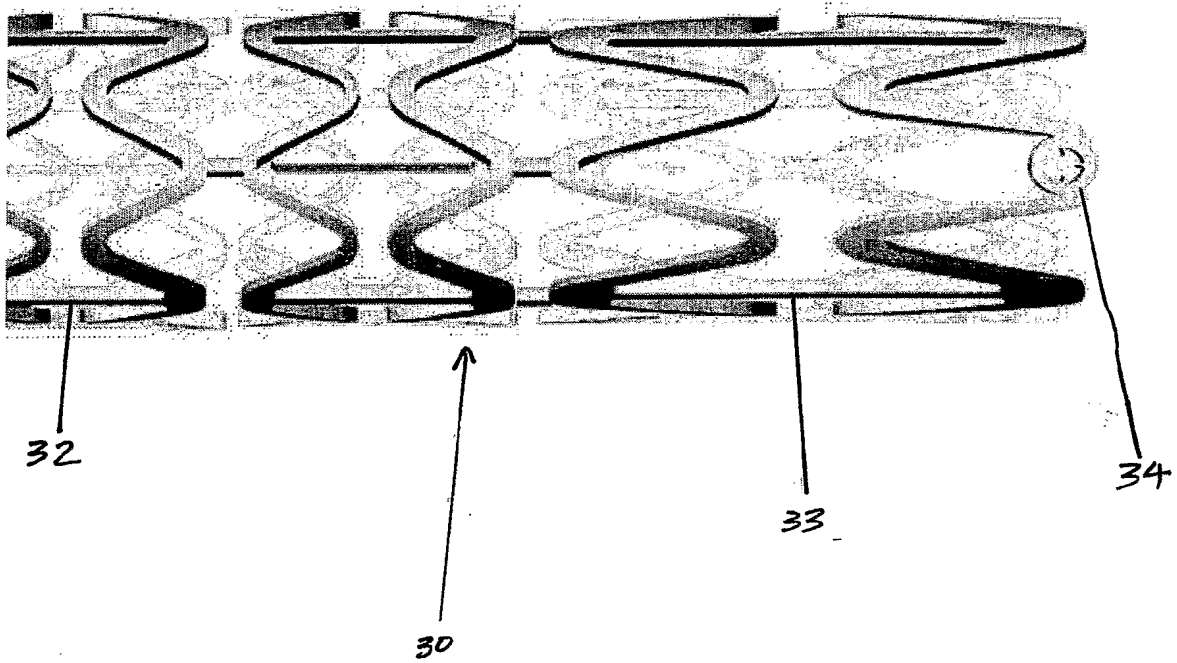


Figure 13

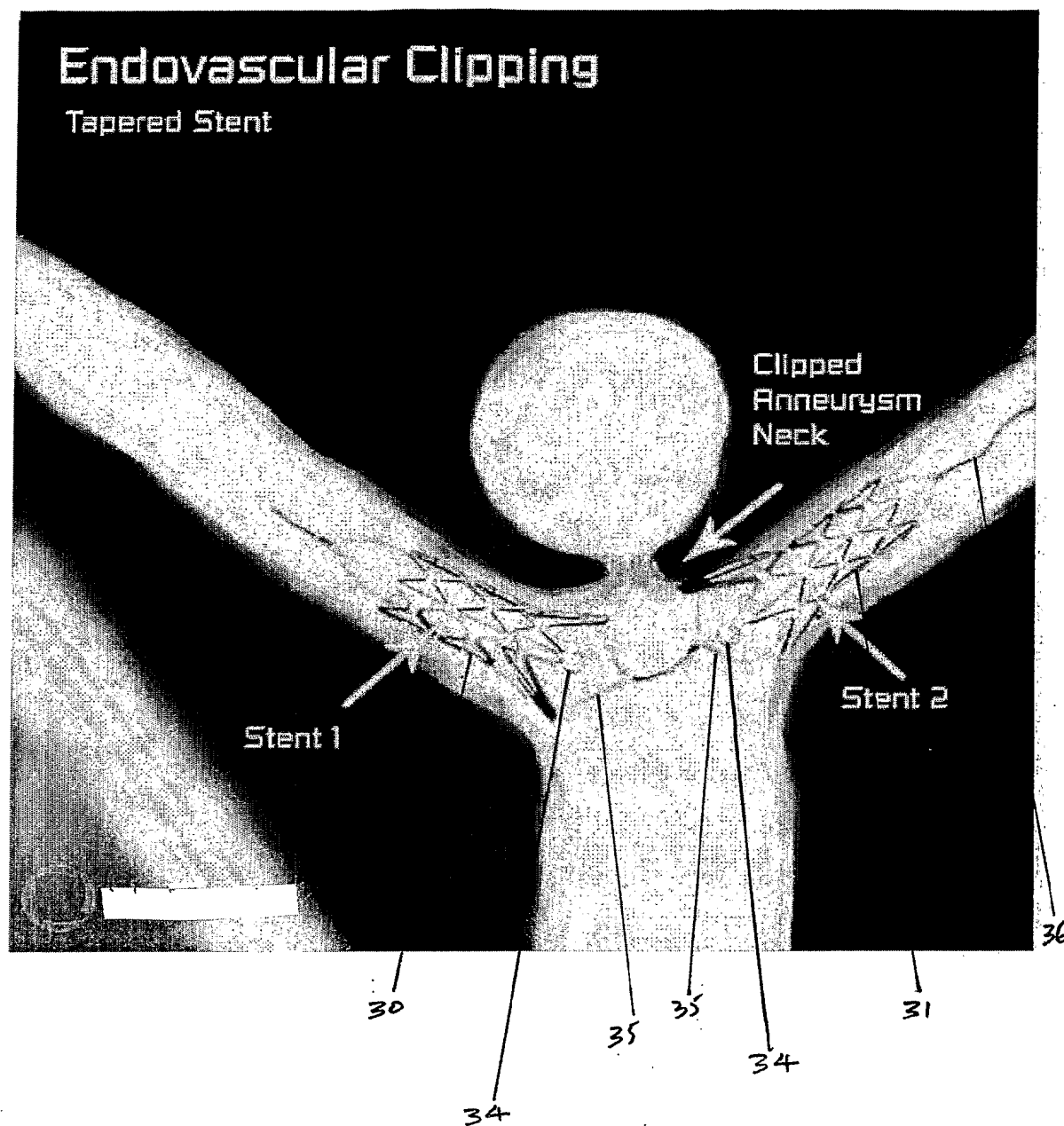
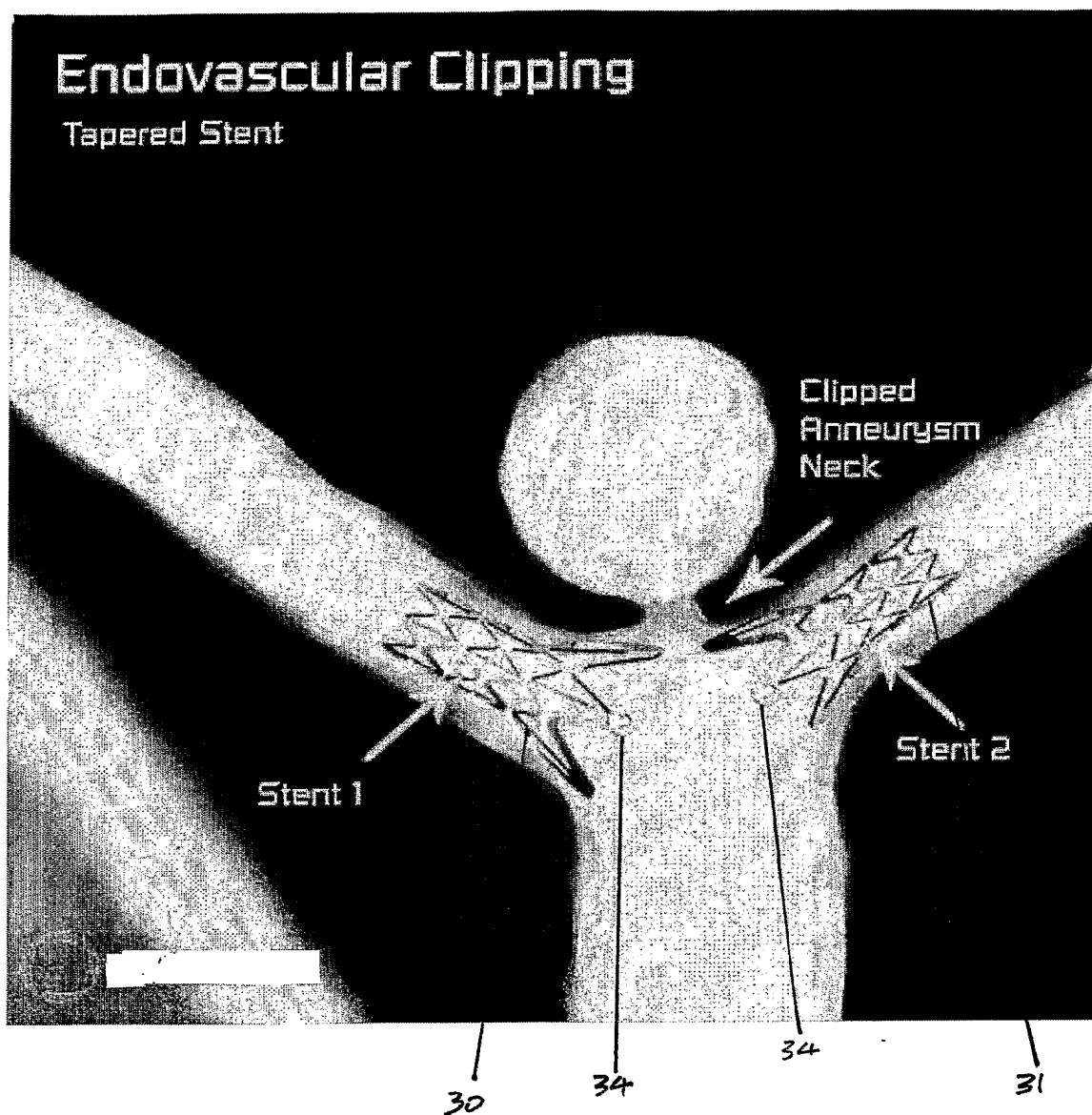
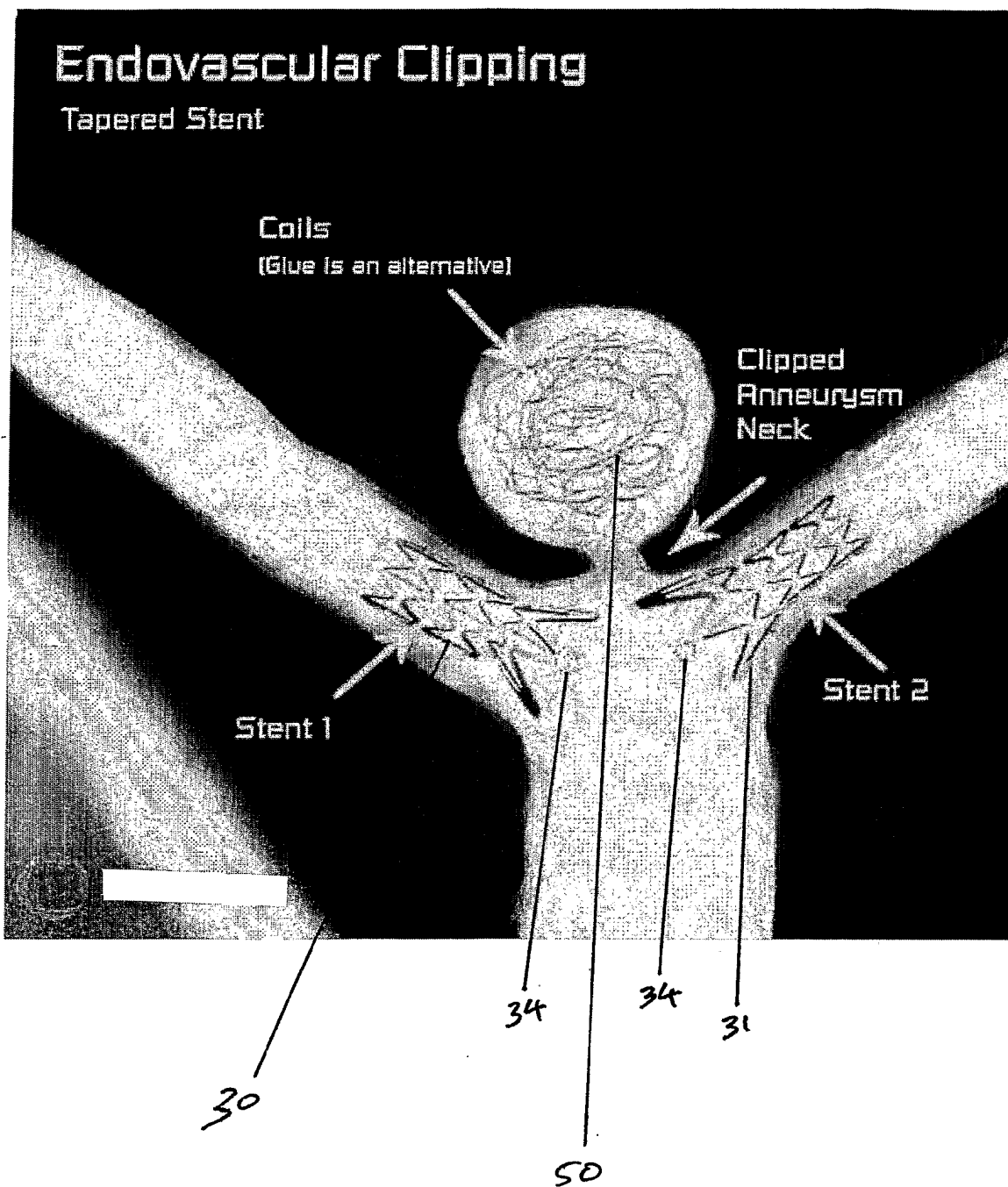


Figure 14



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Figure 15



# INTERNATIONAL SEARCH REPORT

International application No.

**PCT/SG2004/000338**

**A. CLASSIFICATION OF SUBJECT MATTER**

Int. Cl. <sup>7</sup>: A61F 2/06

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DWPI IPC A61B, A61F, A61M and Keywords (aneurysm, occlude, neck, two, stent) and like terms

PUBMED Keywords (bifurcated, aneurysm, occlusion) and like terms

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2003/049600 A2 (STX MEDICAL INC) 19 June 2003 Page 10, lines 18-27, Fig. 5	
A	US 2003/0018294 A1 (COX) 23 January 2003 Para. 54, Fig. 19	
A	US 2002/0042646 A1 (WALL) 11 April 2002 Paras. 36 to 41, Fig. 1	
A	EP 1129666 A1 (CORDIS NEUROVASCULAR INC) 5 September 2001 Para. 22, Fig. 4	

☒ Further documents are listed in the continuation of Box C

☒ See patent family annex

* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search  
**21 January 2005**

Date of mailing of the international search report  
**2 FEB 2005**

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# INTERNATIONAL SEARCH REPORT

International application No.

**PCT/SG2004/000338**

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2000/047134 A1 (NOVO RPS ULC) 17 August 2000 Page 38, line 30 to page 31, line 5, Fig. 6	
A	US 6033435 A (PENN et al) 7 March 2000 Page 13, line 16 to page 16, line 10, Figs. 5-6D	
A	WO 2000/001308 A1 (MICROVENTION INC) 13 January 2000 Page 10, lines 21-26, page 13, lines 11-14, Figs. 6-10	
A	WO 1999/062432 A1 (NEW YORK UNIVERSITY) 9 December 1999 Page 38, line 30 to page 39, line 5, Figs. 6, 14A-19C	
A	WO 1999/058084 A1 (UFLACKER) 18 November 1999 Page 9, line 30 to page 10, line 13, Figs. 4A, 4B	
A	WO 1999/002092 A1 (SCIMED LIFE SYSTEMS INC) 21 January 1999 Page 13, line 16 to page 17, line 8, Figs. 5-6D	
A	Reul, J et al "Long-term Angiographic and Histopathologic Findings in Experimental Aneurysms of the Carotid Bifurcation Embolized with Platinum and Tungsten Coils" American Journal of Neuroradiology 18: 35-42, January 1997	

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/SG2004/000338

## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

## Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:  
See extra sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:  
Claims 1-40

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/SG2004/000338

## Supplemental Box

(To be used when the space in any of Boxes I to VIII is not sufficient)

### Continuation of Box No: III

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1 to 40 relate to a method for treating an aneurysm having an aneurysm neck located proximate to the branching of vessels, comprising positioning a first mechanically expandable device in a first vessel branch proximate to the aneurysm neck, positioning a second mechanically expandable device in a second vessel branch proximate to the aneurysm neck, and expanding the expandable devices to constrict the aneurysm neck such that blood circulation to the aneurysm is reduced. It is considered that positioning a first mechanically expandable device in a first vessel branch proximate to the aneurysm neck, positioning a second mechanically expandable device in a second vessel branch proximate to the aneurysm neck, and expanding the expandable devices to constrict the aneurysm neck comprises a first "special technical feature".
2. Claim 41 relates to a mechanically expandable device for treating an aneurysm having an aneurysm neck comprising a generally tubular construction defined by a plurality of struts having interstitial spaces therebetween, wherein a proximal portion of the struts are elongated relative to the remaining struts such that the device is tapered towards its distal end after deployment. It is considered that the proximal portion of the struts which are elongated relative to the remaining struts such that the device is tapered towards its distal end after deployment comprises a second special technical feature.
3. Claims 42 to 44 relates to a balloon for expanding a mechanically expandable device which is tapered towards its distal end after inflation. It is considered that the balloon being tapered towards its distal end after inflation comprises a third special technical feature.

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.  
**PCT/SG2004/000338**

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member			
WO	2003/049600	US	2003139802		
US	2003/0018294	BR	0211281	CA	2455464
		US	2004186562	WO	03007823
US	2002/0042646	US	6334866	US	6793671
EP	1129666	JP	2001286478	US	6613074
WO	2000/047134	AU	25296/00	CA	2328232
		US	6695876	EP	1071378
US	6033435				
WO	2000/001308	AU	47312/99	BR	9911860
		EP	1093346	US	6165193
		US	2001001835	US	2003083737
WO	1999/062432	AU	43320/99	CA	2334223
		US	6605111	US	6666882
		US	2003060782	ZA	200007149
WO	1999/058084	US	6093203	US	6368355
WO	1999/002092	AU	82904/98	CA	2294735
		US	5951599	EP	0994674
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.					
END OF ANNEX					